

Abstracts

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searched by using PubMed.gov with key words of Validation Health Economics Cancer. Frequencies are tabulated by validation criterion and publication year. Statistical methods employed for testing each validation criteria are summarized. **RESULTS:** Sixty-seven articles are found. 31 articles reveal validation effort. Criteria frequently tested for validation are external validity, internal validity, face validity, criterion validity, content validity, predictive, reliability, responsiveness, sensitivity. Sixty-eight percent of articles were published since 2003 and 89% since 2000. For testing validity of research model, correlation, regression, mean are statistics employed frequently. For testing validity of data, sensitivity & specificity, and positive predictive value are statistics used. **CONCLUSIONS:** Validation effort may have increased since 2003 when guidelines from regulatory agencies have been published. But most articles' validations were partially done. Few articles followed the guidelines to the full extent. In contrast to validation of quality of life instruments, validation of health economics outcomes models lacks theoretical foundation. It is recommended to follow guidelines to enhance credibility of the health outcomes research.

PCN92

VALUATION OF CLINICO-ECONOMIC EFFECTIVENESS OF TREATMENT OF CHILDREN WITH THE NON-HODGKIN LYMPHOMAS (NHLs) ACCORDING TO THE NHL-BFM-95 PROTOCOL

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OBJECTIVES: to estimate medical, social and economic effectiveness of treatment of children with the Non-Hodgkin lymphomas (NHLs) according to the NHL-BFM-95 protocol. **METHODS:** The study included 62 children with NHL, 50 of them with B-cell lymphomas, and 12 with T-cell lymphomas. All children received treatment according to the NHL-BFM-95 protocol. Eighteen children, 12 boys and 6 girls, entered a study group aimed at estimating gained years of quality-adjusted life years. As of January 1st, 2010 the follow-up period comprised 13 years. Survival rates were estimated using the Kaplan-Meier method. **RESULTS:** A 5-year event-free survival of patients treated according to the NHL-BFM-95 protocol for patients with B-cell and T-cell lymphomas was 0.81 ± 0.08 and 0.54 ± 0.14 respectively. Chemotherapy complications appear to be the main reason for mortality during program treatment which is a rate of controlled mortality correlating with the quality of the accompanying treatment. The assumed number of quality-adjusted life years were estimated for each of the patients considering the known disease outcome. A total of 657 years of quality-adjusted life years were saved for 18 patients with NHL treated according to the NHL-BFM-95 protocol; therefore the average rate is 36.5 years. This rate could be used for cost-effectiveness analysis of treatment as a proof of expensive treatment advisability for society from cost perspective. In 2009, the Republic children's clinical hospital (Izhevsk) conducted a survey on clinico-economic cost of treatment of children with NHL according to the NHL-BFM-95 protocol. The cost of one patient illness appeared to be US\$29,550. The method of cost-effectiveness analysis on this medical technology with the calculation of saved years of employability and GDP produced during this time (US\$1356 estimated) demonstrates its social effectiveness. **CONCLUSIONS:** The performed clinico-economic analysis proves medical, social and economic effectiveness of treatment of children with NHL according to the NHL-BFM-95 protocol.

PCN93

COST-EFFECTIVENESS ANALYSIS OF BENDAMUSTINE COMPARED TO ALEMTUZUMAB AND CHLORAMBUCIL FOR CHRONIC LYMPHOCYTIC LEUKEMIA IN A TREATMENT-NAIVE POPULATION

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OBJECTIVES: Bendamustine and alemtuzumab are approved for treatment of chronic lymphocytic leukemia (CLL) in the US, and both are more expensive than chlorambucil. This analysis evaluated the cost-effectiveness of bendamustine (100 mg/m²/day intravenously, for 6 28-day cycles) vs. alemtuzumab (30 mg intravenously, for 12 weeks) vs. chlorambucil (0.8 mg/kg/day orally, for 12 cycles) in first-line treatment of CLL in the US. **METHODS:** The model was a discrete event simulation from a payer perspective, discounted at 3% annually with a lifetime horizon. Simulated patients were assigned baseline characteristics, treatment response, risk of adverse events, and infections based on data from 2 pivotal trials (Knauf et al, 2007; Knauf et al, 2009: bendamustine; Hillmen et al 2007: alemtuzumab) and supplemented by literature. Progression-free survival (PFS) and survival were predicted using survival functions derived from the bendamustine trial data. Resource use, costs (2009 US\$), and utilities were from US databases and literature. **RESULTS:** The median PFS for bendamustine, alemtuzumab, and chlorambucil were 24, 15, and 11 months, respectively, and the total costs/patient were \$75,243, \$113,350, and \$38,700, respectively. The incremental life years (LY) and quality-adjusted life years (QALYs) for bendamustine vs. chlorambucil were 0.89 and 0.72, respectively, resulting in incremental cost-effectiveness ratio (ICER) of \$50,763/QALY. Bendamustine was dominant over alemtuzumab, i.e., the incremental LYs and QALYs for bendamustine were 0.73 and 0.57, respectively, at lower costs. Sensitivity analyses over a wide range of parameters indicated that bendamustine was dominant over alemtuzumab in all scenarios. The ICERs for bendamustine vs. chlorambucil ranged between \$44,819 and \$62,624/QALY. **CONCLUSIONS:** Treatment of CLL with bendamustine costs less and provides better health outcomes compared to alemtuzumab. Although bendamustine led to higher costs vs. chlorambucil, bendamustine was associated with an additional year of PFS,

and the estimated ICER was within the acceptable, threshold commonly used in the US of \$50,000-\$100,000/QALY.

PCN94

COST-MINIMIZATION ANALYSIS OF BIOPSY-BASED RISK STRATIFICATION TOOLS IN INTERMEDIATE-RISK PROSTATE CANCER PATIENTS

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OBJECTIVES: Prostate Cancer (PCa) disease management for intermediate-risk patients is challenging due to the uncertainty in risk at the time of biopsy. Novel prognostic tools that better estimate the risk of disease progression post-biopsy may save costs and improve quality of life by directing patients to more appropriate treatments. We analyzed the cost of PCa management for patients stratified as intermediate-risk by American Urological Association (AUA) guidelines. Management strategies were modeled according to standard care and following a new prognostic tool, Prostate P_x®+. The new test employs morphologic and biomarker features, in addition to the AUA clinical-pathologic ones, to predict PCa disease progression at biopsy. **METHODS:** A cost-minimization analysis was performed on a multi-institution cohort of 399 AUA intermediate-risk patients. P_x+ reclassified 69% of patients as low-risk and 31% as high-risk. A decision analysis model was developed, accounting for five primary treatments (radical prostatectomy (RP), radiation therapy, primary hormonal therapy, brachytherapy and active surveillance) plus secondary treatments. Standard management for AUA intermediate-risk was compared with management post P_x+ reclassification. Patients reclassified as low-risk were assumed to follow low-risk treatment distributions and disease progression; those reclassified as high-risk were assumed to follow high-risk treatment distributions and disease progression. The model was informed with costs and probabilities from the literature and analyzed from Medicare's perspective with a 10 year time horizon. **RESULTS:** The expected cost per patient of standard management was \$30,287 and \$27,987 for P_x+ (including the \$2,968 list price), resulting in an expected cost savings of \$2,300. One-way sensitivity analysis confirmed that modeled management post P_x+ saves costs for all variables except for certain values of recurrence probabilities post RP in low-risk and intermediate-risk patients. **CONCLUSIONS:** Novel personalized risk assessment tools such as P_x+ improve PCa risk stratification, impacting disease management and potentially saving costs over current standards.

PCN95

COST-EFFECTIVENESS OF SEROTONIN-TYPE 3 RECEPTOR ANTAGONISTS FOR CHEMOTHERAPY-INDUCED EMESIS IN NON SMALL CELL LUNG CANCER PATIENTS RECEIVING CISPLATIN-BASED CHEMOTHERAPY

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OBJECTIVES: To determine, from the societal perspective, the relative cost-effectiveness of four serotonin-type-3 receptor antagonists (5HT₃-RA's), palonosetron, ondansetron, granisetron, and dolasetron, for chemotherapy-induced nausea and vomiting (CINV) in patients with non-small cell lung cancer (NSCLC) receiving cisplatin-based chemotherapy. **METHODS:** A Markov model simulating monthly cycles was used to estimate lifetime costs and QALY's gained by each of the interventions. Costs and utilities were discounted by 3% annually. Transition probabilities were estimated using clinical trial results. The study population included a hypothetical cohort with advanced NSCLC receiving cisplatin-based chemotherapy. In accordance with National Comprehensive Cancer Network guidelines, first-line therapy for CINV included a 5-HT₃ RA. Prochlorperazine was used for breakthrough episodes. Direct costs (2009 US\$) included medication costs, adverse events, health care professional fees, hospitalizations, laboratory fees, and cancer progression costs. Indirect costs included the opportunity cost of medical visits. Average life expectancies were calculated from clinical trial results, adjusting for population-based life expectancies. Life years were weighted using utility scores elicited from the general public via a standard gamble technique. **RESULTS:** Assuming a societal cost-effectiveness threshold of \$150,000/QALY, ondansetron and granisetron were cost-effective relative to no treatment, at \$103,759/QALY and \$128,426/QALY, respectively. The incremental cost-effectiveness ratio (ICER) between ondansetron and granisetron was \$310,249/QALY. Dolasetron was dominated by ondansetron and granisetron. Palonosetron was not cost-effective at \$799,696/QALY. In the threshold analysis, granisetron would need to cost \$13.70/month to be cost-effective relative to ondansetron. The model was sensitive to changes in utility values and transition probabilities, resulting in a greater than 50% change in the estimated ICER. In addition, a 50-100% increase in chemotherapy efficacy resulted in a 40-70% change in the ICER. **CONCLUSIONS:** For US patients with NSCLC on cisplatin-based chemotherapy, ondansetron is the most cost effective antiemetic. Generic granisetron is cost-effective relative to no antiemetics and at \$13.70/month or less, would be cost-effective relative to ondansetron.